REMARKS

In conjunction with a Request for Continuing Examination submitted herewith, Claim 30 has been cancelled in lieu of Claim 37, newly submitted, and the remaining Claims amended where appropriate to depend therefrom. In Claims 31 and 32, the abbreviation "BChe" has been replaced with the full designation "butyrylcholinesterase". The preamble of Claims 31 - 36 is amended to replace "a" with "The". Application note the suggestion in the Final Office Action for this amendment with appreciation. Applicants further note with appreciation the courtesies extended to Applicants' representative in the telephonic interview held December 7, 2005. Reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

The rejection of Claims 30-36 under the second paragraph of 35 U.S.C. §112 is obviated by the amendment to replace "a" with "The" as noted above, and by the cancellation of Claim 30 in view of the submission of Claim 37. It is respectfully submitted that the rejection will not apply to Claim 37 because step (iv) in Claim 37 correlates with the preamble in that it recites a determination that is indicative of Alzheimer's disease in the patient.

The rejection of Claims 30-36 under the first paragraph of 35 U.S.C. §112 is obviated by the cancellation of Claim 30 in lieu of Claim 37, newly submitted. It is respectfully submitted that the rejection would not apply to Claim 37. The subject invention is predicated on the discovery by Applicants that patients with Alzheimer's disease have a form of butyrylcholinesterase that possesses an altered glycosylation pattern when compared to the form of butyrylcholinesterase typically found in patients not afflicted with Alzheimer's disease. Accordingly, butyrylcholinesterase with an altered glycosylation pattern acts as a biomarker for the detection of Alzheimer's disease. The subject method based on this premise is reflected in Claims 31 to 37.

Applicants respectfully note that in, in the Office Action mailed September 27, 2004, the Examiner states that the present specification is enabled for a method for diagnosis of Alzheimer's disease in a patent comprising the steps of providing a sample of biological fluid from the patent, detection the presence of butyrylcholinesterase in the sample, detecting the presence of butyrylcholinesterase unbound to both concanacalin A (ConA) and Lens culinaris (LCA) lectins, determining the percent butyrylcholinesterase unbound to both ConA and LCA, wherein an increase in the percentage of butyrylcholinesterase unbound to ConA and a decrease in the percentage of butyrylcholinesterase unbound to LCA as compared to normal is indicative of Alzheimer's disease. Claim 37, newly submitted, reflects this method, with the exception of the recitation of butyrylcholinesterase unbound to LCA.

As is evident from Table 1 in Applicants' specification, butyrylcholinesterase with an altered glycosylation pattern as a biomarker for Alzheimer's disease displays differential bindings to both Con A and LCA lectins, i.e. differential binding as compared to normal butyrylcholinesterase. However, as is also evident from Table 1, while the presence of a different binding pattern to ConA is specific to the butyrylcholinesterase that is a biomarker for Alzheimer's disease, the differential binding pattern to LCA is not specific, note columns 4 and 5 of the LCA binding which indicate that the increased binding of butyrylcholinesterase to LCA may be indicative of Alzheimer's disease or non-AD type dementia (DNAT) or other neurological disorders (ONO).

Presumably, while not wishing to be bound by a particular theory, a patient afflicted with ONO or DNAT may also have a form of butyrylcholinesterase that demonstrates reduced binding of LCA. That such may be the case is clearly evident from the data presented in Table 1 in Applicants' specification at page 8. It follows, therefore, that binding to LCA lectins cannot be utilized as a diagnostic screen for

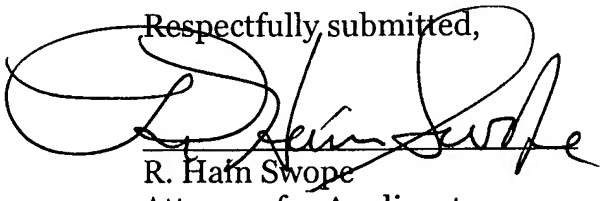
Alzheimer's disease as binding for it is not specific to Alzheimer's disease. Hence, because binding to ConA is a specific indicator of Alzheimer's disease, it is evident that Applicants' method, as embodied in Claims 31-37, is properly limited to only a recitation of an increase in the amount of butyrylcholinesterase unbound to ConA.

It is noted that the rejection of Claim 30 under the first paragraph of 35 U.S.C. §112 was focused on step (iv) thereof. It is respectfully submitted that step (iv) of Claim 37, newly submitted, is clearly supported by Applicants' specification. The first part of step (iv) of Claim 37, i.e. determining the percentage of butyrylcholinesterase unbound to ConA, finds support in the second full paragraph on page 4, lines 13 to 15, of the present specification. The second part of step (iv) is implicit in the teachings in the specification that a decrease in butyrylcholinesterase unbound to ConA compared to normal is indicative of Alzheimer's disease in the patient. The data given in Table 1 on page 8 of the present specification clearly provides a teaching that, compared to normal, i.e. the control, an increase in butyrylcholinesterase unbound to ConA is indicative of Alzheimer's disease in the patient. In view whereof, withdrawal of the rejections is in order and is respectfully requested.

Accordingly, as Claims 31 through 37 meet the requirements of paragraphs one and two of 35 U.S.C. §112, it is respectfully submitted that the above-identified patent application is in condition for allowance. An early Notice of Allowance is respectfully solicited. However, in the event the Examiner is of the opinion that further discussion of the foregoing amendments would be warranted, Applicants' representative would welcome the opportunity for a telephonic discussion.

A Petition for a three month Extension of Time with the requisite fee is submitted herewith thereby providing for the timely filing of this Amendment.

Respectfully submitted,



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